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EXAMINER	
ROONEY, NORA MAUREEN	
ART UNIT	**PAPER NUMBER**
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/517,052	FERREIRA ET AL.	
	Examiner	Art Unit	
	Nora M. Rooney	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) *5-14,16,17 and 21-37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,15 and 18-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 December 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/03/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-37 are pending.

2. Applicant's election without traverse of Group I, claims 1-4, 15 and 18-20 in the reply filed on 06/01/2007 is acknowledged.

3. Claims 5-14, 16-17 and 21-37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Groups, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 06/01/2007.

4. Applicant's IDS filed on 12/03/2004 is acknowledged.

Claim Objections

5. Claims 1-4, 15 and 18-20 are objected to because of the following informalities:

Claims 1-4 refer to the allergen without a proper article preceding the word. The Examiner suggests amending the claims to recite "an allergen" or "the allergen" where appropriate.

6. Claim 3 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claim 1 recites an allergen consisting of a polypeptide. However, claim 3 fails to further limit the allergen claim 1 that "consists" of a polypeptide because the allergen of claim 3 "comprises" the amino acid sequence as shown in SEQ ID NO:1. Applicant is required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form.

Appropriate correction is required.

Claim Rejections - 35 USC § 101

7. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 1-4 and 19-20 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter, a product of nature.

The instant claims are drawn to an allergen. As written, the claim reads on naturally occurring allergen. Amending the claim to recite 'isolated allergen' that does not occur in nature would obviate this rejection.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 15 and 18-20 recite the limitations 'polypeptide as claimed in any one of claims 1 to 4', 'polypeptide of claim 1' and 'polypeptide of claim 3'. There is insufficient antecedent basis for this limitation in the claim because claims 1 and 3 are directed to an allergen, not to a polypeptide. The Examiner suggests amending claims 15 and 18 to recite 'the allergen as claimed in any one of claims 1 to 4', claim 19 to recite 'The allergen of claim 1" and claim 20 to recite 'The allergen of claim 3.'

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 1-4, 15 and 18-20 *are* rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for: an allergen consisting of SEQ ID NO:1, a composition comprising the allergen and a kit thereof, does not provide reasonable enablement for: An allergen consisting of a polypeptide **comprising a fragment of at least 18 consecutive amino acids of the amino acid sequence as shown in SEQ ID NO: 1** of claim 1; Allergen according to claim 1, wherein said fragment is **capable of binding to IgE antibodies from an individual**

being allergic against mugwort pollen of claim 2; Allergen according to claim 1 or 2, **comprising** the amino acid sequence as shown in SEQ ID NO: 1 of claim 3; Allergen of claim 1, characterized in that it is **capable of binding to IgE antibodies from an individual being allergic against ragweed pollen** of claim 4; A **pharmaceutical composition** comprising a polypeptide as claimed in any one of claims 1 to 4 of claim 15; A kit for the diagnosis, treatment or **prevention** of an allergic disorder comprising a polypeptide as claimed in any one of claims 1 to 4 of claim 18; The polypeptide claim 1, wherein the polypeptide is **capable of binding to IgE antibodies from an individual being allergic against ragweed pollen** of claim 19; The polypeptide of claim 3, wherein the polypeptide is **capable of binding to IgE antibodies from an individual being allergic against ragweed pollen** of claim 20.

The specification disclosure does not enable one skilled in the art to practice the invention without an undue amount of experimentation.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the lack of sufficient working examples, the unpredictability in the art and the amount of experimentation required to enable one of skill in the art to practice the claimed invention.

On pages 14-20 of the specification, Applicant discloses the purification, screening,

cloning, sequencing and recombinant expression of the 40.9 kDa mugwort pollen allergen of SEQ ID NO:1. Sera from mugwort allergic patients were also tested for reactivity to the 40.9 mugwort pollen allergen in vitro.

Applicant has not adequately disclosed an allergen consisting of a polypeptide comprising a fragment of at least 18 consecutive amino acids of SEQ ID NO:1. The term "comprising" opens up the claimed polypeptide to encompass any number of undisclosed amino acids added onto the N- and/or C- terminus of the peptide of SEQ ID NO:1. Therefore, the allergenic properties of the polypeptide maybe due to the additional undisclosed amino acid sequence and not to the peptide of SEQ ID NO:1 at all. Further, the specification fails to provide which core structures of SEQ ID NO:1 are essential for IgE binding. Given the lack of sufficient guidance and predictability in determining IgE binding, it would require an undue amount of experimentation for one of skill in the art to arrive at the breadth of the claimed invention. Blumenthal et al. (PTO-892, Reference U) teaches that correlations between structure and IgE binding (or the lack of IgE binding) cannot be predicted on an a priori structural basis (In particular, entire document and page 39 of third full paragraph). Skolnick et al. (PTO-892, Reference V) teaches that sequence-based methods for function prediction are inadequate and knowing a protein's structure, i.e., amino acid sequence, does not necessary tell one its function (In particular, abstract, entire document). Attwood et al. (PTO-892, Reference W) teaches that protein function is context-dependent and the state of the art of making functional assignments merely on the basis of some degree of similarity between sequences and the current structure prediction methods is unreliable (In particular, entire document). Given the lack of guidance as

to which specific amino acids within the polypeptide of SEQ ID NO:1 bind IgE and which amino acids can be added that also might bind IgE, it is unpredictable which polypeptide would exhibit the characteristics of an allergen with IgE binding. Absent the ability to predict which of these polypeptides would function as claimed, and given the lack of data on regions critical for activity, for one of skill in the art to practice the invention as claimed would require a level of experimentation that is excessive and undue.

It is unclear whether or not the claimed allergen polypeptide would function as pharmaceutical composition. In view of the absence of a specific and detailed description in Applicant's specification of how to effectively use the pharmaceutical composition as claimed, and absence of working examples providing evidence which is reasonably predictive that the claimed pharmaceutical composition is effective for in vivo use, and the lack of predictability in the art at the time the invention was made, an undue amount of experimentation would be required to practice the claimed pharmaceutical composition with a reasonable expectation of success.

Further at issue is whether or not the claimed method would function to "prevent" allergy. The specification provides no in vivo data to support the claimed subject matter. The specification fails to provide guidance as to how to totally prevent (100% prevention) allergy using a kit with the composition comprising a peptide of 18 or more consecutive amino acids of SEQ ID NO:1. The invention may reduce the likelihood of an allergy by administering the compound of SEQ ID NO:1, 3, 4 or 5, but the specification does not disclose how to totally prevent allergy. Therefore, the specification does not provide sufficient guidance on how to

sufficiently prevent the occurrence of allergy by administering the claimed compound.

Reasonable correlation must exist between the scope of the claims and scope of the enablement set forth. In view on the quantity of experimentation necessary the limited working examples, the nature of the invention, the state of the prior art, the unpredictability of the art and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

13. Claims 1-4, 15 and 18-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is in possession of: an allergen consisting of SEQ ID NO:1.

Applicant is not in possession of: An allergen consisting of a polypeptide **comprising a fragment of at least 18 consecutive amino acids of the amino acid sequence as shown in SEQ ID NO: 1** of claim 1; and an allergen according to claim 1 or 2, **comprising** the amino acid sequence as shown in SEQ ID NO: 1 of claim 3.

Applicant has disclosed only an allergen consisting of SEQ ID NO:1; therefore, the skilled artisan cannot envision all the contemplated allergen possibilities recited in the instant claims. Consequently, conception cannot be achieved until a representative description of the

structural and functional properties of the claimed invention has occurred, regardless of the complexity or simplicity of the method.

Adequate written description requires more than a mere statement that it is part of the invention. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC1993). The Guidelines for the Examination of Patent Application Under the 35 U.S.C.112, ¶ 1"Written Description" Requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 20001, see especially page 1106 3rd column).

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Applicant is directed to the final Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 1-4 and 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Nilsen et al. (PTO-892, Page 2, Reference U) as evidenced by http://www.allergen.org/allergen.aspx (PTO-892, Reference X) and GenBank Accession Number AY904433 (PTO-892, Page 2, Reference V).

Nilsen et al. identifies an approximately 44 kDa polypeptide allergen in mugwort (Artemisia vulgaris) pollen by SDS-PAGE gel (In particular, Figure 1, approximately 44 kDa bands in lanes C, E, F and K; Table1, whole document). Genbank Accession Number AY904433 and http://www.allergen.org/Allergen.aspx are being used as an evidentiary references to show that the protein of SEQ ID NO:1 is called 'Art v 6' and has a molecular weight

of approximately 44kDa on SDS-PAGE. Therefore, absent evidence to the contrary, the approximately 44 kDa bands of Figure 1 in Nilsen et al. are the claimed allergen consisting of SEQ ID NO:1. Since the office does not have a laboratory to test the reference allergen, it is applicant's burden to show that the reference allergen is not the allergen recited in the claim. See In re Best, 195 USPQ 430, 433 (CCPA 1977); In re Marosi, 218 USPQ 289, 292-293 (Fed. Cir. 1983); and In re Fitzgerald et al., 205 USPQ 594 (CCPA 1980).

The claimed functional characteristics of Claim 2 (capable of binding to IgE antibodies from an individual being allergic against mugwort pollen), Claim 4 (capable of binding to IgE antibodies from an individual being allergic against ragweed pollen), Claim 19 (capable of binding to IgE antibodies from an individual being allergic against ragweed pollen), and Claim 20 (capable of binding to IgE antibodies from an individual being allergic against ragweed pollen) are inherent properties of the allergen of SEQ ID NO:1.

Claims 1-4 and 19-20 are included in this rejection because determining the sequence of the reference allergen is merely further characterization of a known compound. Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999) "Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art... However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. " The Court further held that "this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art".

The reference teachings anticipate the claimed invention.

16. Claims 1-4 and 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Brandys et al. (PTO-892, Page 2, Reference W) as evidenced by http://www.allergen.org/allergen.aspx (PTO-892, Reference X) and GenBank Accession Number AY904433 (PTO-892, Page 2, Reference V).

Brandys et al. identifies an approximately 44 kDa polypeptide allergen in mugwort (Artemisia vulgaris) pollen by SDS-PAGE gel (In particular, Figure 2C, approximately 44 kDa band in lanes v, c, s, p, whole document). Genbank Accession Number AY904433 and http://www.allergen.org/Allergen.aspx are being used as an evidentiary references to show that the protein of SEQ ID NO:1 is called 'Art v 6' and has a molecular weight of approximately 44kDa on SDS-PAGE. Therefore, absent evidence to the contrary, the approximately 44 kDa bands of Figure 2C in Brandys et al. are the claimed allergen consisting of SEQ ID NO:1. Since the office does not have a laboratory to test the reference allergen, it is applicant's burden to show that the reference allergen is not the allergen recited in the claim. See In re Best, 195 USPQ 430, 433 (CCPA 1977); In re Marosi, 218 USPQ 289, 292-293 (Fed. Cir. 1983); and In re Fitzgerald et al., 205 USPQ 594 (CCPA 1980).

The claimed functional characteristics of Claim 2 (capable of binding to IgE antibodies from an individual being allergic against mugwort pollen), Claim 4 (capable of binding to IgE antibodies from an individual being allergic against ragweed pollen), Claim 19 (capable of

binding to IgE antibodies from an individual being allergic against ragweed pollen), and Claim 20 (capable of binding to IgE antibodies from an individual being allergic against ragweed pollen) are inherent properties of the allergen of SEQ ID NO:1.

Claims 1-4 and 19-20 are included in this rejection because determining the sequence of the reference allergen is merely further characterization of a known compound. Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999) "Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art... However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. " The Court further held that "this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art".

The reference teachings anticipate the claimed invention.

17. Claims 1-4 and 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Hirschwehr et al. (PTO-892, Page 2, Reference X) as evidenced by http://www.allergen.org/allergen.aspx (PTO-892, Reference X) and GenBank Accession Number AY904433 (PTO-892, Page 2, Reference V).

Hirschwehr et al. identifies an approximately 44 kDa polypeptide allergen in mugwort (Artemisia vulgaris) pollen by SDS-PAGE gel (In particular, approximately 44kDa bands in

Figure 1A, bands in lanes 10, 11 and 13; Figure 3A, lanes 6 and 7; and Figure 5, patients A and B; whole document). Genbank Accession Number AY904433 and http://www.allergen.org/Allergen.aspx are being used as an evidentiary references to show that the protein of SEQ ID NO:1 is called 'Art v 6' and has a molecular weight of approximately 44kDa on SDS-PAGE. Therefore, absent evidence to the contrary, the approximately 44 kDa bands of Figures 1A, 3A and 5 in Hirschwehr et al. are the claimed allergen consisting of SEQ ID NO:1. Since the office does not have a laboratory to test the reference allergen, it is applicant's burden to show that the reference allergen is not the allergen recited in the claim. See In re Best, 195 USPQ 430, 433 (CCPA 1977); In re Marosi, 218 USPQ 289, 292-293 (Fed. Cir. 1983); and In re Fitzgerald et al., 205 USPQ 594 (CCPA 1980).

The claimed functional characteristics of Claim 2 (capable of binding to IgE antibodies from an individual being allergic against mugwort pollen), Claim 4 (capable of binding to IgE antibodies from an individual being allergic against ragweed pollen), Claim 19 (capable of binding to IgE antibodies from an individual being allergic against ragweed pollen), and Claim 20 (capable of binding to IgE antibodies from an individual being allergic against ragweed pollen) are inherent properties of the allergen of SEQ ID NO:1.

Claims 1-4 and 19-20 are included in this rejection because determining the sequence of the reference allergen is merely further characterization of a known compound. Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999) "Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art... However, the discovery of a

previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. " The Court further held that "this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art".

The reference teachings anticipate the claimed invention.

18. Claims 1-4 and 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by De La Hoz et al. (PTO-892, Page 3, Reference U) as evidenced by http://www.allergen.org/allergen.aspx (PTO-892, Reference X) and GenBank Accession Number AY904433 (PTO-892, Page 2, Reference V).

De La Hoz et al. identifies an approximately 44 kDa polypeptide allergen in mugwort (Artemisia vulgaris) pollen by SDS-PAGE gel (In particular, approximately 44kDa bands in Figure 3, lanes A and B, Figure 4, lanes A, B and C; whole document). Genbank Accession Number AY904433 and http://www.allergen.org/Allergen.aspx are being used as an evidentiary references to show that the protein of SEQ ID NO:1 is called 'Art v 6' and has a molecular weight of approximately 44kDa on SDS-PAGE. Therefore, absent evidence to the contrary, the approximately 44 kDa bands of Figure 3 in De La Hoz et al. are the claimed allergen consisting of SEQ ID NO:1. Since the office does not have a laboratory to test the reference allergen, it is applicant's burden to show that the reference allergen is not the allergen recited in the claim. See

In re Best, 195 USPQ 430, 433 (CCPA 1977); In re Marosi, 218 USPQ 289, 292-293 (Fed. Cir. 1983); and In re Fitzgerald et al., 205 USPQ 594 (CCPA 1980).

The claimed functional characteristics of Claim 2 (capable of binding to IgE antibodies from an individual being allergic against mugwort pollen), Claim 4 (capable of binding to IgE antibodies from an individual being allergic against ragweed pollen), Claim 19 (capable of binding to IgE antibodies from an individual being allergic against ragweed pollen), and Claim 20 (capable of binding to IgE antibodies from an individual being allergic against ragweed pollen) are inherent properties of the allergen of SEQ ID NO:1.

Claims 1-4 and 19-20 are included in this rejection because determining the sequence of the reference allergen is merely further characterization of a known compound. Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999) "Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art... However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. " The Court further held that "this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art".

The reference teachings anticipate the claimed invention.

19. Claims 1-4 and 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Katial et al. (PTO-892, Page 3, Reference V) as evidenced by http://www.allergen.org/allergen.aspx (PTO-892, Reference X) and GenBank Accession Number AY904433 (PTO-892, Page 2, Reference V).

Katial et al. identifies an approximately 44 kDa polypeptide allergen in mugwort (Artemisia vulgaris) pollen by SDS-PAGE gel (In particular, Figure 5, approximately 44kDa band in lane AV; whole document). Genbank Accession Number AY904433 and http://www.allergen.org/Allergen.aspx are being used as an evidentiary references to show that the protein of SEQ ID NO:1 is called 'Art v 6' and has a molecular weight of approximately 44kDa on SDS-PAGE. Therefore, absent evidence to the contrary, the approximately 44 kDa band of Figure 5 in Katial et al. is the claimed allergen consisting of SEQ ID NO:1. Since the office does not have a laboratory to test the reference allergen, it is applicant's burden to show that the reference allergen is not the allergen recited in the claim. See In re Best, 195 USPQ 430, 433 (CCPA 1977); In re Marosi, 218 USPQ 289, 292-293 (Fed. Cir. 1983); and In re Fitzgerald et al., 205 USPQ 594 (CCPA 1980).

The claimed functional characteristics of Claim 2 (capable of binding to IgE antibodies from an individual being allergic against mugwort pollen), Claim 4 (capable of binding to IgE antibodies from an individual being allergic against ragweed pollen), Claim 19 (capable of binding to IgE antibodies from an individual being allergic against ragweed pollen), and Claim 20 (capable of binding to IgE antibodies from an individual being allergic against ragweed pollen) are inherent properties of the allergen of SEQ ID NO:1.

Claims 1-4 and 19-20 are included in this rejection because determining the sequence of the reference allergen is merely further characterization of a known compound. Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999) "Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art... However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. " The Court further held that "this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art".

The reference teachings anticipate the claimed invention.

20. Claims 1-4, 15 and 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Paulsen et al. (PTO-892, Page 3, Reference W) as evidenced by http://www.allergen.org/allergen.aspx (PTO-892, Reference X) and GenBank Accession Number AY904433 (PTO-892, Page 2, Reference V).

Paulsen et al. identifies an approximately 44 kDa polypeptide allergen in mugwort (Artemisia vulgaris) pollen by gel permeation chromatography (In particular, Figure 6 A and B, approximately 45kDa fractions; 'Gel Permeation Chromatography' section on page 207; Table 1; whole document). Genbank Accession Number AY904433 and http://www.allergen.org/Allergen.aspx are being used as an evidentiary references to show that

the protein of SEQ ID NO:1 is called 'Art v 6' and has a molecular weight of approximately 44kDa on SDS-PAGE. Therefore, absent evidence to the contrary, the approximately 44 kDa fraction of Figure 6A and 6B in Paulsen et al. is the claimed allergen consisting of SEQ ID NO:1. Since the office does not have a laboratory to test the reference allergen, it is applicant's burden to show that the reference allergen is not the allergen recited in the claim. See In re Best, 195 USPQ 430, 433 (CCPA 1977); In re Marosi, 218 USPQ 289, 292-293 (Fed. Cir. 1983); and In re Fitzgerald et al., 205 USPQ 594 (CCPA 1980).

The claimed functional characteristics of Claim 2 (capable of binding to IgE antibodies from an individual being allergic against mugwort pollen), Claim 4 (capable of binding to IgE antibodies from an individual being allergic against ragweed pollen), Claim 19 (capable of binding to IgE antibodies from an individual being allergic against ragweed pollen), and Claim 20 (capable of binding to IgE antibodies from an individual being allergic against ragweed pollen) are inherent properties of the allergen of SEQ ID NO:1.

Claims 1-4 and 19-20 are included in this rejection because determining the sequence of the reference allergen is merely further characterization of a known compound. Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999) "Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art... However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer.

" The Court further held that "this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art".

Claim 15 is included in this rejection because the allergen was eluted from the column with phosphate-NaCl (PBS), which is a pharmaceutically acceptable carrier.

The reference teachings anticipate the claimed invention.

Claim Rejections - 35 USC § 103

21. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

22. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nilsen et al. (PTO-892, Page 2, Reference U), Brandys et al. (PTO-892, Page 2, Reference W), Hirschwehr et al. (PTO-892, Page 2, Reference X), De La Hoz et al. (PTO-892, Page 3, Reference U), Katial et al. (PTO-892, Page 3, Reference V), **or** Paulsen et al. (PTO-892, Reference W) as evidenced by http://www.allergen.org/allergen.aspx (PTO-892, Reference X) and GenBank Accession Number AY904433 (PTO-892, Page 2, Reference V) each in view of U.S. Patent 4,459,360 (PTO-892, Reference A).

Nilsen et al., Brandys et al., Hirschwehr et al., De La Hoz et al., Katial et al., and Paulsen et al. have been discussed *supra*.

The claimed invention differs from the prior art by the recitation of a kit.

U.S. Patent 4,459,360 (The '360 Patent) teaches the use of a diagnostic system for detecting the presence of IgE antibodies for allergy screening. Specifically, the '360 Patent teaches the use of mugwort allergens from Artemisia vulgaris pollen for use in a diagnostic test kit to screen liquid test samples for IgE (In particular, column 2, lines 24-41, column 5, line 15, and claim 6; whole document). The reference teaches that such a kit is an effective allergy screening system, especially useful for screening a large number of allergens at once, and is economical, simple to manufacture, and easy and inexpensive to analyze (In particular, column 8, lines 21-27).

It would have been obvious to one of ordinary skill in the art at the time of invention to use the isolated allergen fraction of Paulsen et al. or the isolated allergen band of Nilsen et al., Brandys et al., Hirschwehr et al., De La Hoz et al. or Katial et al. in a diagnostic kit for allergy screening for that allergen as taught by the '360 Patent because the '360 Patent teaches that such a kit would be economical, easy to analyze and useful as an allergy screening system.

From the reference teachings, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

23. No claim is allowed.

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-9937. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

July 20, 2007
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